

### REMARKS

Claims 1-8, 10-12, 16, 28, 31, and 38-41 are pending in this Application with Claims 10, 11, 16, 28, 31, and 38-40 having been withdrawn from consideration by the Examiner. Claims 1-4 have been amended by listing *inter alia* specific clinical conditions associated with herpes virus infection and by excluding conditions associated with virally induced rashes and lesions as well as other inflammatory dermatological conditions. Support for such amendments can be found throughout the specification including on page 19, lines 1-19. No new matter has been added. Claims 16, 28, 31, and 38-41 have been cancelled. Upon entry of this Amendment and Response, Claims 1-8 and 10-12 will be pending in this application with Claims 10 and 11 having been withdrawn from consideration by the Examiner.

#### **Withdrawal of Rejections**

The rejection of Claim 14 under 35 U.S.C. §112, second paragraph, has been withdrawn by the Examiner in view of cancellation of Claim 14.

The rejection of Claims 1-8 and 12-14 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,532,215, issued to Lezday (the “Lezday Patent”) and U.S. Patent 5,358,721, issued to Guittard et al. (the “Guittard et al. Patent”) has also been withdrawn by the Examiner in view of the amendments to Claims.

#### **Rejection Under 35 U.S.C. §102(b)**

Claims 1, 2, 5-8, and 12 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by the Lezday Patent. In particular, the Office Action alleges:

Lezday teaches AAT topical formulas to treat virally induced rashes and lesions as well as other inflammatory dermatological conditions associated with disease (Example 1, column 7). The conditions treated in this example (rashes and lesions as well as other inflammatory dermatological conditions) are the same as the general term of atopic eczema.

Thus, Lezday anticipates the claimed invention.

Page 4 of the Office Action.

Appropriate claims have been amended *inter alia* by excluding conditions associated with virally induced rashes and lesions as well as other inflammatory dermatological conditions; thereby rendering this rejection moot.

**Rejection Under 35 U.S.C. §103(a)**

Claims 1, 3, 4, and 41 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lezday (US Patent No. 5,532,215). The crux of the rejection appears to be that:

One of ordinary skill in the art at the time of invention would have known that treating herpes infection would also reduce diseases associated with herpes infection and that treating the herpes would prevent the outbreak of herpes associated diseases because the underlying cause, herpes virus infection, is treated.

Thus, it would have been *prima facie* obvious to treat herpes associated diseases by treating herpes as taught by Lezday with the expectation of success because Lezday teaches how to treat herpes and associated conditions with AAT peptides.

Page 5 of the Office Action.

In essence, the Office Action appears to be alleging that prohibiting herpes virus proliferation would treat all the clinical conditions associated with herpes virus infection. The underlying assumption in this logic is that all the clinical conditions associated with herpes virus infection are propagated by the virus itself.

The Lezday Patent is directed to preventing or inhibiting viral proliferation. See, for example, Col. 4, lines 21-27. That is, the Lezday Patent discusses preventing proliferation of virus by inhibiting viral replication. In contrast to the assertion on page 5 of the Office Action, Col. 6, lines 25-36 of the Lezday Patent does **not** teach “that AAT treatment can be used against HIV and viruses associated with other conditions....” That portion of the Lezday Patent appears to merely list viruses that can be inhibited from proliferation by AAT. See also, Col. 5, lines 26-27 (“Alpha 1-antitrypsin have been found to be effective **in the prevention of the proliferation of viruses**...”) (emphasis added). In fact, it appears the symptoms that the Lezday Patent discusses treating are associated with viral infiltration. See, for example, Col. 6, lines 43-45 (“In addition, alpha 2-macroglobulin because of its binding with complements C3a and C5a, which are activated as a result of viral infections, **reduces some of the symptoms of inflammation resulting from the viral infiltration in humans**”) (emphasis added).

While it is possible that some dermatological conditions can indeed be treated by prohibiting herpes virus proliferation or infiltration, it is not true that one can treat clinical conditions such as tumors, cancers, etc. by prohibiting herpes virus proliferation or infiltration. Once these clinical conditions are established, manifestation of these conditions becomes independent of herpes virus itself. Thus, merely preventing or inhibiting viral proliferation will not treat clinical conditions claimed in the presently pending claims.

In contrast to the Lezday Patent, the present inventor has found that a peptide exhibiting mammalian alpha-1 antitrypsin (AAT) or AAT-like activity can be used to treat various clinical conditions associated with a herpes virus infection including those conditions not associated with proliferation or infiltration of herpes virus.

Since the Lezday Patent appears to discuss preventing or inhibiting viral proliferation and treating only those conditions associated with herpes virus proliferation or infiltration, it is submitted that it would not have been obvious to one skilled in the art that clinical conditions associated with herpes virus infection that are not associated with proliferation or infiltration of herpes virus can also be treated with a peptide exhibiting mammalian alpha-1 antitrypsin (AAT) or AAT-like activity.

Accordingly, it is respectfully submitted that the rejection of claims under 35 U.S.C. §103(a) is improper and should be withdrawn.

### CONCLUSION

In view of the foregoing, Applicant submits that all claims now pending in this Application are in condition for allowance. Therefore, an early Office Action to that effect is earnestly solicited. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at (303) 955-8103.

Respectfully submitted  
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